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ATTORNEY DOCKET NO. CONFIRMATION NO. FILING DATE FIRST NAMED INVENTOR APPLICATION NO. 10/708,919 03/31/2004 Mark C. Boomer 101896-0241 2918 **EXAMINER** 7590 06/05/2006 21125 **NUTTER MCCLENNEN & FISH LLP** COMSTOCK, DAVID C WORLD TRADE CENTER WEST PAPER NUMBER **ART UNIT** 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604 3733

DATE MAILED: 06/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)	
Office Action Summary		• •		
		10/708,919	BOOMER ET AL.	
		Examiner	Art Unit	
		David Comstock	3733	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).				
Status				
1)🖂	Responsive to communication(s) filed on 28 Fe	bruary 2006.		
2a) <u></u> □	This action is FINAL . 2b)⊠ This	action is non-final.		
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is			
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.				
Disposition of Claims				
4) Claim(s) 1,2,7-10,13-20,42,43 and 46-50 is/are pending in the application.				
4a) Of the above claim(s) is/are withdrawn from consideration.				
5) Claim(s) is/are allowed.				
· <u> </u>	6)⊠ Claim(s) <u>1,2,7-10,13-20,42,43 and 46-50</u> is/are rejected.			
	7) Claim(s) is/are objected to.			
8) Claim(s) are subject to restriction and/or election requirement.				
Application Papers				
9) The specification is objected to by the Examiner.				
10) The drawing(s) filed on <u>06 September 2005</u> is/are: a) accepted or b) objected to by the Examiner.				
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).				
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.				
Priority under 35 U.S.C. § 119				
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:				
1. Certified copies of the priority documents have been received.				
2. Certified copies of the priority documents have been received in Application No				
3. Copies of the certified copies of the priority documents have been received in this National Stage				
application from the International Bureau (PCT Rule 17.2(a)).				
* See the attached detailed Office action for a list of the certified copies not received.				
Attachmen	t(s)			
1) Notic	e of References Cited (PTO-892)		mmary (PTO-413)	
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) 			/Mail Date ormal Patent Application (PTO-152)	
Paper No(s)/Mail Date <u>12/12/05</u> . 6) Other:				

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DETAILED ACTION

Information Disclosure Statement

The references on the IDS submitted 12 December 2005 were already made of record by Examiner in the Office action mailed 03 June 2005. Regardless, since these references have been considered, a copy of the initialed IDS has been mailed to Applicant.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 8, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7, "the other of the first and second elongate members" lacks clear antecedent basis, since claim 1, from which this claim depends, does not establish which member, i.e. whether the first or the second, is to be a spinal fixation rod. Thus, claim 7 could be read as having the spinal fixation rod as required by claim 1, leaving the nature of another member undefined.

Claim 8, "the other of the first and second elongate members" also lacks clear antecedent basis. If claim 1 refers to both members as spinal fixation rods, then it is unclear what is meant by "the other of the first and second elongate members." In addition, if claim 8 is intended to refer to one member being a rod and the other being a plate, then it would appear to be a redundant duplicate of rejected claim 9.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 13-20, 42, 43, 46, 48 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Lai (5,509,328).

Lai discloses a device comprising a first elongate member 10 having a female connector with opposed arms 13 and a second elongate member 20 having a male connector 40 adapted to mate to the female connector (see Fig 2). The members are adjustably coupled to one another. A locking mechanism locks the elongate members in a fixed position relative to each other. The devices are angularly adjustable in a single plane. The opposed arms define a recess for receiving the male connector. The device includes a bore 14 extending through the opposed arms on the female connector and through the male connector, and a central mating element 51,52 extending through the bore for mating the male and female connectors together. The central mating element comprises a cylindrical member 51. The device rotates about this member when it is in a loosened state. The cylindrical member is fixedly coupled to a portion of the female connector, and the male connector is free to rotate about the cylindrical member when loose. The locking mechanism is effective to engage the cylindrical member to prevent movement of the male connector relative to the female connector when tightened. The locking mechanism comprises a slot 43 extending through the

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male connector such that the male connector is in the form of a clamp, and wherein the locking mechanism further comprises a threaded fastening element 44 adapted to engage the male connector to clamp the cylindrical member within the bore. The female connector and male connector rotate about a central axis extending substantially perpendicular to an axis of the first and second elongate members. The locking mechanism is adapted to extend into a connector along an axis that is substantially parallel to the plane of adjustability. The diameter of the first and second elongate member appears to be substantially the same. A terminal end of the second elongate member is at an angle to a longitudinal axis of the second elongate member.

Claims 46, 48 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Ulrich et al. (4,433,677).

Ulrich et al. disclose a device comprising elongate rods 1 that can be locked at an angle relative to each other by means of a locking mechanism 16, 20 at the ends 9 thereof (see Figs. 2-4). The end of one arm comprises a female connector 11 and the end of the other arm together with the screw 16 comprises the male connector received in the female connector. Thus, one arm is clamped between the other arm and the screw. The angular adjustability occurs in a single plane. The locking mechanism, e.g. the screw, extends along an axis that is perpendicular to the plane of adjustability. The terminal end 9 of each rod is positioned at an angle with respect to its own longitudinal axis, as at the outer curved surface extending at an angle about the outer diameter of the terminal end (see Fig. 2).

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Claims 1, 2, 7-9, 13-16, 20, 42 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Yue (6,007,536).

Yue discloses a device comprising a rod 1 that can be locked at an angle with respect to a plate 2 by means of a locking mechanism 3,4 at the ends of the rod and plate (see Figs. 1A-1C). The device adjusts in a single plane. The plate includes a female connector having arms that receive the male connector (see Fig. 1B). A bore extends through the male and female connector components to allow rotation about a cylindrical member attached to the female connector. Both the plate and rod are capable of being used for spinal applications.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10, 47 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yue (6,007,536).

Yue discloses the claimed invention except for explicitly disclosing different diameters or an offset angle of 90 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the device with differing diameters or with an offset angle of 90 degrees, since it has been held that

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where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claims 47 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ulrich et al. (4,433,677).

Ulrich et al. disclose the claimed invention except for the diameters of the rods specifically being different and the angular position of the end of the rods being about 90 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device with rods having any of numerous ranges of diameters and to provide an angular end position of about 90 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Response to Arguments

Applicant amended the independent claims in an attempt to place them into condition for allowance. In the last action, claims 7 and 8 were objected to as containing allowable subject matter subject to being rewritten in independent form including all the limitations of the base claim and any intervening claims. Claim 7 required that both elongate members comprised a spinal fixation rod. Likewise, claim 8 required that both elongate members comprise a spinal fixation plate. The present amended claims do not include this allowable subject matter. Claim 8, as best

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understood, is essentially the same as rejected claim 9. Amended claim 7 is also unclear and does not necessarily require that both members be spinal fixation rods, as stated above with respect to the rejection under 35 USC 112.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

D. Comstock

SUPERVISORY PATENT EXAMINER